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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,248	10/16/2001	Mark A. Hoffman	CRNC.83071	6008
46169	7590	09/08/2005	EXAMINER	
SHOOK, HARDY & BACON L.L.P. 2555 GRAND BOULEVARD KANSAS CITY, MO 64108-2613			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 09/08/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,248

Applicant(s)

HOFFMAN ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-30, 55-60 and 85-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-30, 55-60, and 85-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

2-00

Claims 25-30, 55-60, and 85-91 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Applicant is advised that should claim 26 be found allowable, new claim 91 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

This objection is necessitated by amendment.

Claim Rejections - 35 USC § 103

Applicant's arguments filed 6/20/05 have been fully considered but they are not persuasive. The arguments are addressed below as they pertain to specific rejections.

Claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) and REINHOF et al. (US 2002/0049772 A1, filed 5/26/2000).

In response to the argument that neither ICHIKAWA nor EVANS teach computerized steps, or a step of "automatic" accessing of a list of risk-associated agents, or "automated computer components" it is noted, as set forth in the previous office action, that REINHOF is relied upon for teaching of a computer-implemented method, system, and medium for performing the method, and that EVANS teaches a list of "risk-associated agents" for use in a

Art Unit: 1631

method similar to that claimed. Applicant is reminded that the rejection is made over a *combination* of references, wherein accessing the list of EVANS in a computer-implemented method, as taught by REINHOFF, is made obvious by the combination of references for the reasons previously set forth and reiterated below. It is further noted that none of the claims specifically recite any "automated" or "automatic" step or component; however, as it appears that applicant equates "computer-implemented" with "automatic", the arguments have been addressed under this interpretation.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is found in REINHOFF, as previously set forth, reiterated below, and repeated in a paragraph quoting the Office Action on page 11 of the response.

In response to the argument that one would not be motivated to combine REINHOFF with (presumably) ICHIKAWA and EVANS because the treatment (agent) is already known, as set forth on page 12 of the response, is not persuasive as (a), the claims do not limit the risk-associated agents to be "unknown", and (b) all of ICHIKAWA, EVANS, and REINHOFF teach that a known drug may also be one which is a "risk-associated agent" when that drug causes adverse side-effects.

In response to applicant's argument with regard to hindsight reasoning and deprecation of the claimed invention, set forth on page 12 of the response, applicant is advised that a finding of obviousness is not an implication that a claimed invention is not a good one, and that the

Art Unit: 1631

motivational statement set forth is in no way intended to deprecate the claimed invention.

Further in response to the argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to the argument that there is no expectation of success in combining the teachings of ICHIKAWA, EVANS and REINHOFF, it is noted that all three teach association of polymorphisms with side-effects or idiosyncratic reactions caused by drugs. As all the references teach similar methods, EVANS teaches a computer-implemented system, and REINHOFF specifically teaches a computerized method of associating a genetic/polymorphic profile with patient response to drugs, the examiner maintains that one skilled in the art would reasonably have anticipated success in combining the teachings of ICHIKAWA, EVANS, and REINHOFF.

Reiterated from the office action of 2/17/05:

"It would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of ICHIKAWA, as taught by REINHOFF, and to have accessed a list of treatment/drug options, as taught by EVANS, in the automated method of ICHIKAWA and REINHOFF, where the motivation would have been to facilitate use of the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by REINHOFF (paragraph 59)."

Claims 28, 58, and 88 are again rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) and REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000).as applied to claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 above, and further in view of FEY et al. (US Pub. 20020038227, filed 2/26/01).

The argument that FEY does not teach a computer system is not persuasive as applicant admits on page 14 of the response that "Data and test results are transmitted to a centralized data management system..." As "transmission" of data is generally considered to by an "automated" process, the "centralized data management system" of FEY is interpreted by the examiner to be a computer system. Further, applicant is reminded that the rejection is made over a combination of references wherein both EVANS and REINHOFF also teach automated systems and computer implementation. FEY is relied upon in the rejection for his teaching of a comprehensive healthcare system/database, not for a teaching of computerized steps.

The argument that there is no suggestion or motivation to combine FEY with the other references is moot as page 14 of the response repeats the motivation set forth in the office action of 2/17/05; i.e. "where the motivation would have been to associate phenotypic information specific for a patient with genotypic information in a clinical setting, in order to better treat/test the patient, as taught by Reinhoff (paragraph 67)."

The argument with regard to "known" agents is not persuasive for the same reasons as those set forth above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
9/1/05